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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,490	12/11/2000	Roger Desmond Drinkwater	13922	6804

7590 05/13/2003

Scully Scott Murphy & Presser
400 Garden City Plaza
Gardner City, NY 11530

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/13/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,490

Applicant(s)

DRINKWATER ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8, 9 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 5-7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 Dec 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I, peptide SEQ ID NO:5 in Paper No. 18 is acknowledged. The traversal is on the ground(s) that . This is not found persuasive because it is stated that the three groups are linked to form a general inventive concept (i.e., the peptide of SEQ ID NO 5, nucleic acid encoding this peptide and antibodies which bind to the peptide). It is also stated that the recited peptides are all derivatives of SEQ ID NO:5. Applicants are reminded that PCT Rules 13.1 and 13.2 do not allow for multiple products. Not only are products known which contain SEQ ID NO:1 or are derived from SEQ ID NO:1, claim, for example, recites numerous sequences for the second loop which *a priori* are portions of multiple proteins (different primary structures) . The claims as a whole are reviewed for of unity. Once a lack of unity has been determined, it is immaterial whether a small portion of the claimed subject matter may be directed to a single inventive concept. The Examiner must deal with all claims that have been presented for examination, not a very small portion of the recited subject matter.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 18.

Information Disclosure Statement

The listing of references in the specification (page 40, line 10-page 43, line 8) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents,

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publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicants on PTO-1449, they have not been considered.

The references submitted by Applicants have been noted and placed in the file; however, as they have not been accompanied by form PTO-1449, they have not been made of record.

Specification

The disclosure is objected to because of the following informalities

The sequences on line 24 of page 30, lines 9-10 of page 31 have not been identified by their corresponding SEQ ID Nos.

On page 31, line 10 is "*Tag*" intended to be "*Taq*"?

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The use of the trademarks VYDAC QIAGEN and SCIEX has been noted in this application (e.g., pages 28, lines 19, 24; page 29, line 10, page 31, line 22, page 33, line 21, etc). Any should be capitalized wherever it appears and be accompanied by the generic terminology.

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Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). The claim, however has been treated on the merits to the greatest extent possible.

Claim 4-6 are objected to because of the following informalities: they recite non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9, 15-16 and 19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the especially disclosed peptides of SEQ ID NOs: 5-7, 14-31 and ω conotoxins that bind to calcium channels and contain the subsequences SEQ ID NOs:1-2, does not reasonably provide enablement for and ω conotoxins comprising 1 or more conservative amino acids or side chain modifications. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. First, it is noted that one could theoretically entirely substitute all of the amino acids of SEQ ID NO:1, so that a peptide encompassed by the claim have no sequence similarity with any of the recited sequences. Second, in claims 1-4 and 14, it is noted that no functional properties, such as specific binding to calcium channels are required for the encompassed peptides. Third, while the definition of conservation substitutions on page 3, lines 1-24 of the specification is noted, it also observed that the definition is not limiting. Thus, one has no way to assess whether a specific peptide which is unrelated in structure, or whether a specific c[protein containing a specific sequence is encompassed within the claims. The Examiner discovered following the search for SEQ ID NO:1 that the peptide of SEQ ID NO:1 (SGTVGR) is a subsequence of many proteins, including the DD peptidase/penicillin binding protein of Streptomyces R61 (Swissprot Accession NO: P15555), an unidentified protein

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of *Methanobacterium thermoautrophicum* (PIR Accession No. B69002), a ferric vibriobactin ABC transporter of *Vibrio cholerae* (PIR accession No. C82281, a chloroplast precursor ERD1 protein of *Arabidopsis thaliana* (Swissprot Accession No. P42762), an unidentified protein of *Drosophila melanogaster* (Accession No. Q94C10), a possible cell wall surface anchor family protein of *Leishmania major* (accession No. Q8WT29), DNA polymerase I of *Mycobacterium leprae* (Swissprot Accession No. P46835), a nuclear DNA binding protein of Marek's disease virus (PIR Accession No. A48725), etc. The instant claims do not specify, for example that SEQ ID NO:1 is directly adjacent to a cysteine at both its NH₂ and the COOH terminus. It thus appears, that the scope of the claims is far broader than the disclosure and undue experimentation be required in order to determine whether a specific peptide or protein falls within the scope of the claims .

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 15-16 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 15-16, and 19 each provide for the use of a conotoxin peptide, but, since not one of these claims does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim 19 is further indefinite as it recites "VSCC". An abbreviation by its nature is considered indefinite; it is suggested that the first occurrence of an abbreviation be accompanied by the full recitation of the term to which it refers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 , 8-9, and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Miljanich *et al.*. (US patent 5424218) > the reference provides for the use of omega conotoxins including MVIIIA in blocking voltage gated calcium channels (see column 9, lines 35-43, treatment of neuronal damage related to ischemia (Example 11), and in screening methods for compounds which bind to calcium channels (columns 9-13). The reference is deemed anticipatory for the claimed subject matter because MVIIIA, by substitution is derived from SEQ ID NO:1, and contains SKLMYD (SEQ ID NO:2) in its second loop) and has been used in binding assays and in pharmaceutical treatment.

Conclusion

No claim is allowed.

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Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The ω -conotoxin of SEQ ID NO:5 is free of the prior art.

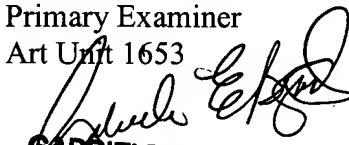
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

May 8, 2003

Gabriele E. BUGAISKY
Primary Examiner
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**GABRIELE BUGAISKY
PRIMARY EXAMINER**